KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, P.L.L.C.
SUMNER SQUARE
1615 M STREET, N.W.
SUITE 400
WASHINGTON, D.C. 20036-3215

(202) 326-7900
FACSIMILE:
(202) 326-7999

April 12, 2023

Via ECF

Honorable Robert C. Chambers
United States District Court for the
Southern District of West Virginia
Sidney L. Christie Federal Building
845 Fifth Avenue, Room 101
Huntington, WV 25701

Re: *GenBioPro, Inc. v. Sorsaia et al.*, No. 3:23-cv-00058 (S.D.W. Va.)

Dear Judge Chambers:

Plaintiff GenBioPro, Inc. ("GenBioPro") respectfully submits this notice of two district court opinions issued on April 7, 2023, pertaining to mifepristone, the drug at issue in this litigation. The first is an order issued in *Alliance for Hippocratic Medicine v. FDA*. That order purports to "stay[ ] the effective date of" the U.S. Food and Drug Administration's ("FDA") "September 28, 2000, Approval of mifepristone," and to stay three additional "challenged [FDA] actions" concerning mifepristone. Memorandum Op. and Order at 67, *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Apr. 7, 2023) ("Texas Order"), Dkt. 137 (capitalization and emphasis omitted). The second is an order issued in *Washington v. FDA*. That order preliminarily enjoins FDA from "altering the status quo . . . relate[d] to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy [('REMS')]." Order Granting in Part Plaintiffs' Motion for Preliminary Injunction at 30, *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. Apr. 7, 2023) ("Washington Order"), Dkt. 80. Neither order provides any basis for this Court to delay ruling on Defendants' motions to dismiss the instant action nor precludes the parties from litigating the merits of this case. Both orders likely will trigger appeals processes that could take years to resolve. In the meantime, West Virginians should not have to live under an unconstitutional state-law regime.

First, neither order addresses the issues in this litigation. Neither addresses whether Congress, in enacting the Food and Drug Administration Amendments Act of 2007 ("FDAAA") and providing that mifepristone be "deemed" to have in effect an approved REMS, preempted state restrictions on access to mifepristone. FDAAA § 909(b)(1), 121 Stat. at 950-51, *reprinted*

at 21 U.S.C. § 331 note. Indeed, the Texas Order does not mention the 2023 REMS. Neither opinion addresses the Commerce Clause.

Second, West Virginia's Unborn Child Protection Act remains preempted by federal law and continues to violate the Commerce Clause, preventing the sale of GenBioPro's FDA-approved mifepristone in West Virginia. *See* Plaintiff's Opposition to Defendant Patrick Morrisey's Motion to Dismiss at 1-2, 8-27 (Mar. 17, 2023) ("Opp. to Morrisey MTD"), Dkt. 35. The Texas Order purports (at 67) to preliminarily "stay" the 2019 approval of GenBioPro's abbreviated new drug application, but the Texas court stayed its own order for seven days to permit appellate review. FDA sought a stay in the Fifth Circuit, further delaying the effective date of the Texas Order. *See* Emergency Motion Under Circuit Rule 27.3 for a Stay Pending Appeal, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 10, 2023), Dkt. 20. And the Washington Order simply prevents FDA from altering the status quo with respect to mifepristone's 2023 REMS. *See* Washington Order at 30. Although the court intended its order to apply only in the plaintiff states, *id.* at 29, because FDA cannot preserve the REMS in some states but not others, the order necessarily dictates nationwide policy.

Third, the Texas Order (at 32-38) rested its "stay" of FDA's 2021 decision to eliminate the in-person dispensing requirement in an earlier version of the Mifepristone REMS on the Comstock Act of 1873, *see* 18 U.S.C. §§ 1461-1462, a statute on which the West Virginia Attorney General erroneously relies in his motion to dismiss. *See* Memorandum in Support of Motion to Dismiss at 8, 15, 17, 20 (Feb. 21, 2023), Dkt. 20; Opp. to Morrisey MTD at 6-7. But the Texas court's holding on this point is incorrect, as numerous Department of Justice officials have noted, including former U.S. Attorneys General and the former U.S. Attorney for the Southern District of West Virginia. *See* Brief of Former U.S. Dep't of Justice Officials as *Amici Curiae* Supporting Appellants' Motions to Stay the District Court Ruling Pending Appeal at 3, 28, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 12, 2023) ("Former DOJ Officials' Brief"), Dkt. 116 (calling the Texas court's interpretation of the Comstock Act "gravely incorrect" and explaining that "the Comstock laws are irrelevant to the validity of FDA's actions, however those laws are interpreted").

Congress considered mifepristone expressly when enacting the FDAAA. *See* Brief of Food and Drug Law and Health Law Scholars as Amici Curiae in Support of Plaintiff's Opposition to Defendants' Motions to Dismiss at 8 (Mar. 27, 2023), Dkt. 44 ("[O]n the Senate floor, two Senators discussed the fact that, pursuant to the text of FDAAA, mifepristone would be distributed under a deemed REMS."). As members of Congress themselves have explained, "Congress was well aware that mifepristone would be included under [the REMS program]" when it passed the law and "made no exception for it." Brief of 240 Members of Congress as *Amicus Curiae* in Support of Defendants-Appellants' Emergency Motion for a Stay Pending Appeal at 11-12, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 11, 2023), Dkt. 62-2. Moreover, Congress was familiar with the longstanding line of cases holding that the Comstock Act does not forbid shipping products "employed by conscientious and competent

physicians." *United States v. One Package*, 86 F.2d 737, 739 (2d Cir. 1936); Opp. to Morrisey MTD at 6; *see* Former DOJ Officials' Brief at 20-21. Members of Congress understood the Comstock Act not to forbid the mailing of FDA-approved prescription drugs subject to a REMS. The Texas Order interpreted the Comstock Act in a manner conflicting with the longstanding judicial and congressional understanding and failed to consider Congress's inclusion, in the FDAAA, of mifepristone as an FDA-approved drug subject to a REMS. *See* Opp. to Morrisey MTD at 6-7.[1]

Copies of the Texas Order and the Washington Order are enclosed as Exhibits A and B, respectively, for the Court's convenience.

Respectfully submitted,

/s/ David C. Frederick
David C. Frederick*
**admitted pro hac vice*

/s/ Anthony J. Majestro
Anthony J. Majestro
WV Bar No. 5165
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com

Counsel for Plaintiff GenBioPro, Inc.

[1] Pharmaceutical industry leaders condemned the Texas Order as "fundamentally undermin[ing] the bipartisan authority granted by Congress to [FDA] to approve and regulate safe, effective medicines for every American." Christina Jewett, *Drug Company Leaders Condemn Ruling Invalidating F.D.A. Approval of Abortion Pill*, N.Y. Times (Apr. 10, 2023), https://www.nytimes.com/2023/04/10/health/abortion-ruling-pharma-executives.html (see linked letter).